

### REMARKS

The invention described and claimed in this application is one of many discoveries that one or more of applicants have made concerning reducing the growth of unwanted hair. See also, for example, Ahluwalia et al. (AA); Shander et al. (AE); Shander et al. (AF); Ahluwalia et al. (BA); Ahluwalia (BB); Breuer et al. (BC); Shander (BD); Shander et al. (DI); Ahluwalia et al. (DJ); and Ahluwalia (DK).

The present invention relates to angiogenesis, which in the development of new blood vessels. There are at least seven pathways that are known to be involved in angiogenesis. These pathways, and the various established ways to interfere with the pathways in order to inhibit angiogenesis, are discussed extensively by applicants in the Background and Summary of the Invention sections of the application.

Generally, applicants conceived that if they could inhibit angiogenesis in an area of skin, they could cause a reduction in the amount of hair growth from that area of skin. Applicants wanted to test their concept and accordingly searched the literature to find chemicals that are known to be inhibitors of angiogenesis, or of the biochemical pathways involved in angiogenesis. They selected 19 compounds for evaluation. The selected compounds were dissolved in the appropriate vehicle, and applied topically as described on pages 9-12 of the specification. Every compound that applicants tested as part of this project caused a reduction in hair growth. See the results on pages 11-12 of the specification (Table 1).

The compounds tested by applicants inhibit angiogenesis in a variety of ways, as explained in the specification. For example, catechin is an inhibitor of the enzyme sulfotransferase; pentosan polysulfate is a heparin binding antagonist; cimetidine is a histamine receptor antagonist; and piracetam is an inhibitor of prostogladin synthetase.

Claim 1 is a method claim directed to the generic invention. Claim 1 requires (1) selecting an area of skin from which reduced hair growth is desired, and (2) applying an inhibitor of angiogenesis to that area of skin in an amount effective to cause a reduction in hair growth.

Thus, applicants have made a significant and broad contribution to the art, have conducted substantial testing to demonstrate their contribution, and have submitted a claim (claim 1) that is commensurate in scope with their contribution.

35 U.S.C. §112, ¶2 Rejection

Claims 1, 8, 21-29, 42, and 43 were rejected under 35 U.S.C. §112, ¶2 because applicants used the word "inhibiting" in the claims. Specifically, the claims require "inhibiting hair growth."

Applicants do not agree that "inhibiting hair growth" is ambiguous, but in the interests of advancing prosecution have replaced "inhibiting" with "reducing" in the claims. What is meant by reducing hair growth is described expressly in the specification (see page 9, lines 3-18), and also is a phrase well-understood in the art. See, for example, the patents related to reducing hair growth cited above.

According to 35 U.S. C. §112, ¶2,

[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which applicant regards as his invention.

As the Court explained in In re Wakefield, 164 U.S.P.Q. 636, 641 (C.C.P.A. 1970):

The meaning of this provision is simply that an applicant is required to set definite boundaries on the patent protection sought.

The purpose of the requirements of 35 U.S.C. §112, ¶2 is

to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with the adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance.

In re Hammack, 166 U.S.P.Q. 204, 208 (C.C.P.A. 1970).

For the above reasons, a person skilled in the art would understand what is meant by reducing hair growth. As a result, the claims satisfy the requirements of 35 U.S.C. §112, ¶2.

#### 35 U.S.C. §112, ¶1 Rejection

The Examiner also had rejection claims 1, 8, 21-29, 42, and 43 under 35 U.S.C. §112, ¶1 for failing to provide an enabling disclosure. Despite the presence of 19 working examples (including a composition containing mycophenolic acid), and experimental data demonstrating that the examples actually work to reduce hair growth (see Table 1), the Examiner says applicants have not established that inhibitors of angiogenesis can be used

to reduce hair growth. In particular, the Examiner says (p. 4 of office action):

As the cited reference provided with this Office Action discloses mycophenolic acid contrary to being a hair growth inhibitor is a hair growth stimulating compound and thus one of ordinary skill in the art could not practice the invention as claimed. The Examiner notes applicant's specification appears to be a shotgun specification for a whole slew of compounds and mycophenolic acid has not been disclosed or specifically singled out for inhibition of hair growth but appears to be only a "paper example" of an active which is contemplated or will be obtained at some future date experimental data showing mycophenolic acid as useful in inhibiting hair growth. However, prophetic test systems are not considered to provide any basis for presuming that the claimed method of treating using mycophenolic acid is enabled in mammalian subjects or human hosts.

Applicants request that this rejection be reconsidered and withdrawn.

The Examiner's concern about a "shotgun specification for a whole slew of compounds" is unfounded. As explained previously, the 19 examples tested by applicants contain compounds that are established inhibitors of angiogenesis, or of the pathways involved in angiogenesis, and all caused a significant reduction in hair growth. Most of the compounds used in the examples are unrelated, except for their connection with pathways involved in angiogenesis. Thus, the specification is not a "shotgun disclosure" of a "whole slew" of unrelated compounds, but rather a broadly enabling description of the types of compounds that can inhibit angiogenesis, with substantial

experimental testing that establishes that the compounds actually work to reduce hair growth.

The Examiner appears concerned that reference L, cited with the Office Action, seems to teach that mycophenolic acid can be used to stimulate hair growth. But applicants have actually tested mycophenolic acid and found that applied topically it reduces hair growth. Moreover, as mentioned previously, applicants also have tested 18 other inhibitors of angiogenesis and found that all can be used to reduce hair growth. Thus, regardless of the teaching of reference, applicants have established that topical application of mycophenolic acid -- and inhibitors of angiogenesis generally -- reduce hair growth.

Finally, the Examiner apparently believes that the test that applicants used in the specification -- the Golden Syrian hamster assay -- is a "prophetic test system," whatever that means. But this assay has long been accepted in the art (and in the Patent and Trademark Office) as an acceptable model for evaluating whether compositions can be used to reduce hair growth. See the references cited at the beginning of this amendment, as well as Wiechart (CA) and Ferrario (CB). Accordingly, the Examiner's dismissal of the Golden Syrian hamster assay as "prophetic" is wrong.

In the event the Examiner decides to maintain this basis for the 35 U.S.C. §112, ¶1 rejection, applicants request a detailed explanation of why the Examiner believes this assay is no longer an acceptable model for evaluating the ability of compounds to reduce hair growth.

Conclusion

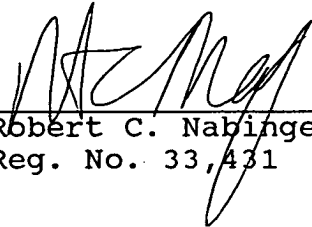
Applicants submit that the claims are in condition for allowance, and such action is requested. A petition for a one month extension of time for responding to the July 8, 1996 action, and the petition fee, are enclosed.

Please apply any other charges or any credits to our deposit account number 06-1050.

Respectfully submitted,

Date:

06/28/96

  
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